Telefax: +41 71 775 80 99



Safety Data Sheet

according to UK REACH Regulation

els unibond

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Saremco cements and auxiliary bonding promotors are intended for the indirect reconstruction or correction of functionally compromised natural dentition

Uses advised against

None.

1.3. Details of the supplier of the safety data sheet

Company name: Saremco Dental AG
Street: Gewerbestrasse 4
Place: CH-9445 Rebstein
Telephone: +41 71 775 80 90

e-mail: info@saremco.ch

Contact person: Dr. Christoph Evers Telephone: +41 71 775 80 60

e-mail: Christoph.evers@saremco.ch

Internet: www.saremco.ch

Responsible Department: Vigilance

1.4. Emergency telephone CH: 145

<u>number:</u> Ausland: +41 44 251 51 51

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 STOT SE 3; H335 Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

10-Methacryloyl-oxydecyl-dihydrogenphosphat

BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BISEMA

Signal word: Warning

Pictograms:



Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.



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Precautionary statements

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P501 Dispose of contents/container to an appropriate recycling or disposal facility.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name				
	EC No	Index No	REACH No		
	Classification (GB CLP Regulation)			
64-17-5	ethanol; ethyl alcohol			25 - < 50 %	
	200-578-6	603-002-00-5			
	Flam. Liq. 2, Eye Irrit. 2; H225 H31	9	•		
85590-00-7	10-Methacryloyl-oxydecyl-dihydrogenphosphat				
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3				
41637-38-1	BISPHENOL A POLYETHYLENE	ATE, BisEMA	10 - < 25 %		
	609-946-4				
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens.	35			
	Acrylpolymer; Degacryl 4779 L		1 - < 5 %		
	Eye Irrit. 2; H319				
128-37-0	Butylated hydroxitoluene		0.1 - < 1 %		
	204-881-4				
	Aquatic Chronic 1; H410				

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

Opecine Conc. Limits, M-ractors and ATE					
CAS No	EC No	Chemical name	Quantity		
	Specific Conc.	onc. Limits, M-factors and ATE			
64-17-5	200-578-6	ethanol; ethyl alcohol	25 - < 50 %		
	inhalation: LC50 = 95,6 mg/l (vapours); oral: LD50 = 6200 mg/kg				
85590-00-7		10-Methacryloyl-oxydecyl-dihydrogenphosphat	25 - < 50 %		
	oral: LD50 = > 2000 mg/kg				
128-37-0	204-881-4	Butylated hydroxitoluene	0.1 - < 1 %		
	oral: LD50 = >	6000 mg/kg			

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.





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After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Observe risk of aspiration if vomiting occurs. Rinse mouth immediately and drink 1 glass of of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.



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Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Saremco Dental-Haftvermittler fördern die Haftung von direktem oder indirektem Zahnersatz zur Rekonstruktion oder Korrektur von funktionell beeinträchtigten natürlichen Zähnen.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10	·	TWA (8 h)	WEL
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL

8.2. Exposure controls





Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid Colour: yellow

Melting point/freezing point: not determined Boiling point or initial boiling point and not determined

boiling range:

not determined Flammability: Lower explosion limits: not determined Upper explosion limits: not determined > 150 °C Flash point: Auto-ignition temperature: not determined Decomposition temperature: not determined pH-Value: not determined Water solubility: The study does not need to be conducted because the substance is known to be

insoluble in water.

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined Vapour pressure: not determined 1.3 g/cm³ Density (at 20 °C): Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation



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Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
64-17-5	ethanol; ethyl alcohol					
	oral	LD50 mg/kg	6200	Ratte	IUCLID	
	inhalation (4 h) vapour	LC50	95,6 mg/l	Ratte	RTECS	
85590-00-7	10-Methacryloyl-oxydecyl-dihydrogenphosphat					
	oral	LD50 mg/kg	> 2000	Rat		
128-37-0	Butylated hydroxitoluene					
	oral	LD50 mg/kg	>6000	rat		OECD 401

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BISEMA)

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

 $\label{lem:may-cause} \mbox{May cause respiratory irritation.} \ \ (\mbox{10-Methacryloyl-oxydecyl-dihydrogenphosphat})$

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name						
	Aquatic toxicity Dose [h] [d] Species Source Method						
64-17-5	ethanol; ethyl alcohol						
	Acute crustacea toxicity	EC50 9268 - 14221 mg/l	48 h	Daphnia magna	IUCLID		

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.



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Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol; ethyl alcohol	-0,31

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)

Other applicable information (air transport)

No dangerous good in sense of these transport regulations.

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40

Information according to 2012/18/EU

Not subject to 2012/18/EU (SEVESO III)

(SEVESO III):



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National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile

work protection guideline' (94/33/EC).

Water hazard class (D): -- non-hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration. 50%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

RID: Regulations concerning the international carriage of dangerous goods by rail MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container VOC: Volatile Organic Compounds SVHC: Substance of Very High Concern

@1605.B000001

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification for mixtures and asea evaluation method according to CD CE. Regulation				
Classification	Classification procedure			
Skin Irrit. 2; H315	Calculation method			
Eye Irrit. 2; H319	Calculation method			
Skin Sens. 1; H317	Calculation method			
STOT SE 3; H335	Calculation method			
Aquatic Chronic 3; H412	Calculation method			

Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.



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H315	Causes skin irritation.			
H317	May cause an allergic skin reaction.			
H319	Causes serious eye irritation.			
H335	May cause respiratory irritation.			
H410	Very toxic to aquatic life with long lasting effects.			
H412	Harmful to aquatic life with long lasting effects.			
Further Information	•			

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)